

and frequencies simulating various physiological conditions at the start and after 100 million cycles.

Results: Analysis was performed with transapical Jenavalve prostheses (27mm) implanted in circular annuli (n=3) or annuli with 0.84 eccentricity (n=3). Hydrodynamic testing showed no significant difference in valve performance with regard to the average regurgitation volume under both conditions at the start [circular: $4.69\pm 0.20\%$; oval: $4.81\pm 0.25\%$ of total stroke volume; $p=n.s.$] Interestingly after a durability test of 100 million cycles hydrodynamic testing showed a slightly reduced average regurgitation volume in the oval annulus [circular: $5.53\pm 0.19\%$; oval: $3.59\pm 0.39\%$ of total stroke volume; $p=n.s.$]. Macroscopic analysis and histology revealed no difference between valve leaflets of the two groups.

Conclusions: This is the first experimental in vitro durability study demonstrating no significant difference in valve performance and regurgitation volume for a percutaneous valve implanted in an eccentric annulus.

TCT-752

Asian Comparative Outcomes of Balloon-Expandable versus Self-expandable valves for Transcatheter Aortic Valve Implantation

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Background: The aim of this study is to compare the clinical outcomes after transcatheter aortic valve implantation (TAVI) with the Edwards SAPIEN/SAPIEN XT transcatheter heart valve (ESV) versus the Medtronic CoreValve (MCV) in Asian countries.

Methods: The data from databases of 3 Asian centers were pooled and analyzed. Study objectives were Valve Academic Research Consortium outcomes at 30 days and 1 year. In total, 185 patients were included: 86 (46.5%) treated with the ESV and 99 (53.5%) with the MCV.

Results: Previous PCI, previous CABG and peripheral artery disease were more frequent in ESV group but aortic annulus area and perimeter measured by MDCT were larger in MCV group. There were no differences in baseline echocardiographic findings and calcification grade. Device success occurred in 78 of 86 patients (90.7%) in ESV group and 74 of 99 (74.7%) patients in MCV group (relative risk [RR], 1.21; 95% confidence interval [CI]: 1.40 to 7.75; $p=0.005$). This was attributed to a significantly lower frequency of residual more-than-mild aortic regurgitation (7.2% vs. 16.0%; RR, 0.45; 95% CI 0.90 to 6.61; $p=0.07$) and the less frequent need for implanting more than 1 valve (0% vs. 10.1%; $p=0.002$). All-cause mortality at 30 days was 4.7% in ESV group and 2.0% in MCV group (RR, 2.35; 95% CI, 0.42 to 13.33; $p=0.42$). Stroke, bleeding and vascular complications were not significantly different, and the combined safety end point occurred in 14.0% in ESV group and 10.1% in MCV group (RR, 1.39; 95% CI, 0.59 to 3.53; $p=0.42$). Placement of a new permanent pacemaker was less frequent in the ESV group (1.2% vs. 22.2%, $p<0.001$). At 1 year, there were no difference in all-cause mortality (8.6% vs. 8.5%; hazard ratio [HR], 0.77; 95% CI, 0.28 to 2.23; $p=0.61$) and combined efficacy endpoint (15.1% vs. 22.2%; RR, 0.68; 95% CI, 0.29 to 1.33; $p=0.22$).

Conclusions: Among patients with aortic stenosis undergoing TAVI in Asian countries, the use of ESV resulted in a greater rate of device success than use of MCV, however combined safety endpoint at 30 days, and all-cause mortality and combined efficacy endpoint at 1 year were similar between 2 groups.

TCT-753

Efficacy and Feasibility of On-pump Transcatheter Aortic Valve Implantation in Patients with Severely Decompensated Heart Failure

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Background: Although transcatheter aortic valve implantation (TAVI) has widened the indication for the treatment of aortic valve stenosis (AS), there is still a group of patients considered 'extremely high-risk', including those with severely decompensated heart failure. The aim of this study is to evaluate the early results of TAVI under cardiopulmonary bypass support (CPS) (on-pump TAVI) in patients with severely decompensated heart failure.

Methods: Among 157 cases from October 2009 through April 2014, twelve patients (7.6%) were treated by on-pump TAVI using SAPIEN/SAPIEN XT. Mean age was 81 ± 6 years and left ventricular ejection fraction (LVEF) was significantly low (33 ± 7). Ten patients (83%) were dependent on catecholamine support and one patient (8.3%) was required CPS preoperatively. Mean preoperative BNP was significantly high (1562 pg/ml). EuroSCORE was $62\pm 25\%$ and STS score was $27\pm 23\%$.

Results: Urgent procedure was required in three cases (25%). Transapical procedure was performed in three cases (25%). Procedural success was 100% and CPS was removed in operating room in all patients (pump time, median: 13 minutes). One patient was died from coronary event 3 postoperative day. There were no thromboembolic and neurologic complications. Ten patients (83%) were discharged to home. LVEF at 1-month was significantly improved (49%, $p<.05$). The 30-day mortality was 8.3% and survival at 6- and 12-months were 91% and 78%, respectively (mean follow-up period, 332 ± 277 days).

Conclusions: We achieved satisfactory early and short-term outcomes of on-pump TAVI. On-pump TAVI may become the standard therapy to treat aortic valve stenosis in the presence of severely decompensated heart failure.

TCT-754

Predictors For Tissue Embolization During Transcatheter Aortic Valve Implantation

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Background: Cerebrovascular embolization is frequent during Transcatheter Aortic Valve Implantation (TAVI). The aim of this study was to identify variables associated with tissue embolization during TAVI.

Methods: A total of 82 patients underwent TAVI with a dual filter-based embolic protection device (Montage Dual Filter System, Claret Medical, Inc) deployed in the brachiocephalic trunk and left common carotid artery. Both balloon expandable and self-expanding transcatheter heart valves (THV) were used. After TAVI the filters were retrieved and sent for histopathologic analysis.

Results: Overall, debris was captured in 86% of patients. Captured material varied in size from 0.1 to 9.0 mm. Thrombotic material was found in 74% of patients and tissue-derived debris in 63%. Tissue-derived debris was found more often with balloon expandable THV (79% vs. 56%, $p=0.05$). The dislodged material corresponded best with dislodged tissue from the native aortic valve leaflets, aortic wall or left ventricular myocardium. Balloon-expandable THV (adjusted OR: 12.100; 95% CI 1.925-76.040, $p=0.008$) and cover index (adjusted OR: 1.151, 95% CI 1.015-1.307, $p=0.029$) were independent predictors for tissue embolization by multivariable logistic regression analysis.

Conclusions: Debris is captured with filter-based embolic protection in the vast majority of patients undergoing TAVI. Tissue derived material is found in 63% of cases and is correlated with the use of balloon expandable systems and more oversizing.

TCT-755

Trancatheter Aortic Valve Implantation in Patients with Pure Severe Native Aortic Regurgitation: Results after 3 Year of Follow-Up

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Background: Trancatheter Aortic Valve Implantation (TAVI) is an option to treat pure severe aortic regurgitation (PSAR) in patients at high surgical risk. We hereby report the 3-year follow-up (3-y FU) of patients with inoperable PSAR treated in our Institute using Medtronic CoreValve prosthesis.

Methods: Aortic valve sizing was assessed on 3 dimensional-CT scan considering perimeter, area, major and minor orthogonal annular diameter. An oversizing prosthesis with respect of annular perimeter was used. We developed a size table (see below) to choose the right valve dimension. Sixteen pts with PSAR underwent TAVI with CoreValve prosthesis (mean age 84 ± 2.6 ; mean L-Euroscore 33%)

Valve Size	23 mm	26mm	29mm	31mm
Annulus Diameter [mm]	N/A	D \geq 19 D \leq 21	D \geq 21 D \leq 24	D \geq 24 D \leq 27
Annulus Perimeter [cm]	N/A	P \geq 5,9 P \leq 6,6	P \geq 6,7 P \leq 7,7	P \geq 7,8 P \leq 8,5

Results: A procedural success has been reached using a single valve in 13 pts. In these pts we observed an improved functional capacity and no death at a 3-y FU. In one case a second valve deployment (CoreValve 29 mm in Core-Valve 31 mm) was necessary to reduce the peri-leak severe aortic regurgitation obtaining a final moderate grade of aortic regurgitation. In this case we observed a worsening of NYHA class after 1-y FU and frequent re-hospitalizations for congestive heart failure at 3-y FU. In 2 cases conversion to emergency open surgery and aortic valve replacement was required due to residual severe aortic regurgitation despite a second valve deployment. These 2 pts died 1 year after the procedure (one from infective endocarditis and one from acute pulmonary edema). A new permanent PM implantation was necessary in 7 pts.